CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
**DEPARTMENT OF STATE**
DIVISION OF PROFESSIONAL REGULATION
**BOARD OF PHARMACY**

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: DPR.DELAWARE.GOV

# APPLICATION FOR DISTRIBUTOR (PHARMACY-WHOLESALE) PERMIT

## INSTRUCTION SHEET

### When to File Application

This is the application for facilities that distribute on a wholesale basis:

- Drugs, toilet preparations, dentifrices, and cosmetics to persons other than the ultimate consumer (24 *Del. C*. §§2540)
- Medical gases ***to other facilities*** authorized to possess medical gases.

Note: If you are a facility that sells medical gases ***directly to patients*** in Delaware, the correct application form is *Application for Medical Gas License*.

File this application for a Pharmacy-Wholesale license when applying for an initial license OR re-applying when a previous Delaware license has lapsed and is no longer renewable. Since these licenses are not transferable, you must also file this application to report when a distributor already licensed in Delaware:

- Changes ownership (controlling interest), or
- Relocates.

A Pharmacy-Wholesale permit terminates automatically when the controlling interest in the facility changes, the facility's legal existence ends, or the business ceases to operate (24 *Del. C*. §2540 (d)).

### How to Apply

Please read and follow instructions carefully. Failure to follow instructions may delay your application.

☐ Submit completed, signed and notarized *Application for Distributor (Pharmacy-Wholesale) Permit*.
- Applications that are incomplete, unsigned or not notarized will be rejected.

☐ Enclose non-refundable processing fee by check or money order made payable to the "State of Delaware."

☐ Enclose *Distributor Permit–Information About Ownership* forms for ***all*** of the following:
- Designated Representative (DR) or most senior person responsible for facility operations, purchasing, and inventory control
- Supervisor of the DR or most senior person responsible for facility operations, purchasing and inventory control
- If the distributor is not a publicly held company, ***all*** principals and owners who directly or indirectly own more than 10% interest in the company

☐ Arrange for the Board office to receive a federal and state criminal background check for *each* person who is required to submit the *Distributor Permit–Information About Ownership* form. Each of these persons must complete an *Authorization to Release Information* form and follow the instructions on the form to submit his or her fingerprints.
- The background checks must be sent directly from the State Bureau of Identification to the Board office.

☐ If the facility is not located in Delaware, arrange for the Board office to receive a *License Verification for Distributors* form from the licensing agency for the state where the facility is located.

☐ Enclose a drawn plan and full description of this distributor's site—including each area utilized for drug storage, distribution, or both—*at this location*. The description should include:
- square footage
- security and alarm system descriptions
- terms of lease or ownership
- quarantined area for damaged, outdated, deteriorated, misbranded, or adulterated drugs
- temperature and humidity controls.

☐ Enclose a copy of the deed or lease for the property on which the wholesale distributor's establishment is located.
- If leased, the lease must be for an original term of not less than one calendar year.

☐ If the distributor is a repackager or manufacturer with the Food and Drug Administration, enclose a copy of the regulatory letter.

**Reporting a Distributor Name Change**

If the facility's name changes, but ***there is no change in ownership nor in location***, it is not necessary to submit an *Application for Distributor (Pharmacy-Wholesale) Permit*. Instead, submit:

☐ Letter notifying the Board of the change that includes the distributor's old name and new name, license number and effective date of the change.

☐ Duplicate license fee by check or money order made payable to the "State of Delaware."
- The duplicate license will show the new name, but the license number will not change.

**Controlled Substances Registration**

If the facility also distributes controlled substances, a separate *Controlled Substances Application for Facilities* application is required.

**A distributor must have a Delaware Distributor (Pharmacy-Wholesale) permit, Delaware controlled substance registration and federal DEA permit before storing and/or distributing controlled substances in Delaware.**

**For Board of Pharmacy Use Only**
- ☐ **Verification**
- ☐ **Background**
- ☐ **Office Approval**
- ☐ **Inspection**

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# APPLICATION FOR DISTRIBUTOR (PHARMACY-WHOLESALE) PERMIT

## TYPE OF APPLICATION

1. Select the items that describe the type of application:

   ☐ Initial Application –
   - ☐ This distributor has never held a Delaware Pharmacy-Wholesale license.
   - ☐ This distributor previously held Pharmacy-Wholesale license number **A4-** _____ that has lapsed and is no longer renewable.

   ☐ Application Due to Change of Ownership – Pharmacy-Wholesale license number **A4-** _____

   ☐ Application Due to Relocation of Facility – Pharmacy-Wholesale license number **A4-** _____

2. Select type of items distributed: ☐ Drugs ☐ Medical Gases ***Only***

## CONTACT AND LOCATION INFORMATION

3. Name of Business (as it should appear on license): _____

4. Enter all other trade or business names you use (or have used) such as "doing business as" or "formerly known as" names: _____ _____ _____

5. ***Location*** **Address**: _____
   Street (*No PO Boxes*)

   _____ _____ _____
   City State Zip

   **Enclose a drawn plan and full description of this distributor's site—including each area utilized for drug storage, distribution, or both—*at this location*. See Instruction Sheet for details that must be included in the description. Also, attach a copy of the deed or lease for the property on which the wholesale distributor's establishment is located. If leased, the lease must be for an original term of not less than one calendar year.**

6. Phone: _____ Email: _____

7. ***Mailing*** **Address** (*if different from physical location*): _____

   _____ _____ _____
   City State Zip

## INFORMATION ABOUT OWNERSHIP

8. Form of Business (check one)

   ☐ Partnership
   ☐ Sole Proprietorship
   ☐ Individual with federal employee identification number
   ☐ Corporation

9. Enter the name of the Designated Representative (DR) or most senior person responsible for facility operations, purchasing, and inventory control: _____ **Enclose a *Distributor Permit–Information About Ownership* form for this person. This person must also submit federal and state criminal background checks.**

10. Enter the name of the supervisor of the person named above: _____ **Enclose a *Distributor Permit–Information About Ownership* form for this person. This person must also submit federal and state criminal background checks.**

11. Is this distributor a publicly held company? Yes ☐ No ☐ **If no, list the names of the principals and owners who directly or indirectly own more than 10% interest in the company.**

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

**Enclose a *Distributor Permit–Information About Ownership* form for *each* person listed. In addition, *each* of these persons must submit federal and state criminal background checks.**

**LICENSURE HISTORY**

12. Does the distributor hold any state or federal licenses, registrations, or permits authorizing the wholesale distributor to purchase, possess and distribute drugs? Yes ☐ No ☐ **If yes, attach a list of license/registration/permit numbers and the jurisdiction that issued them.**

    **If the distributor is not located in Delaware, arrange for the Board office to receive a *License Verification for Distributors* form from the licensing agency for the state where the facility is located.**

13. Has this wholesale distributor ever been disciplined by any state or federal agency? Yes ☐ No ☐ **If yes, attach a list of all disciplinary actions by state and federal agencies against the wholesale distributor.**

**POLICIES AND PROCEDURES**

14. Are the policy and procedures required by Section 8.0 of the Board's Rules and Regulations and the FDA available on site for inspection? Yes ☐ No ☐

**REPORTING CHANGES**

15. Do you agree to report any changes in the foregoing information to the Board office, in writing, within 30 days of the change as required by Section 8.2.1. of the Board's Rules and Regulations? Yes ☐ No ☐

**CONTROLLED SUBSTANCES**

16. Will you distribute controlled substances? Yes ☐ No ☐

**A distributor must have a Delaware Distributor (Pharmacy-Wholesale) permit, Delaware controlled substance registration and federal DEA permit before storing and/or distributing controlled substances in Delaware.**

**REPACKAGER/MANUFACTURER INFORMATION**

17. Are you a repackager or manufacturer with the Food and Drug Administration? Yes ☐ No ☐ **If yes, enter the following information and enclose a copy of the regulatory letter**

    Registration Number: _____ Date of Last GMP Inspection: _____

**When your application is complete, please allow 4-8 weeks to receive your license. A complete application is one that includes all required documentation and correct payment.**

**Applications that are not complete within six (6) months of filing may be considered abandoned and discarded.**

## AFFIDAVIT

I do hereby make application to the Board of Pharmacy for license or registration under the provisions of an Act to regulate the practice of Pharmacy in the State of Delaware and solemnly swear and affirm that the answers to the questions set forth in this application are true and correct.

Printed Name: _____ Title: _____

**Signature:** _____ Date: _____

State of _____ County of _____

Subscribed and sworn to before me this_____day of_____, 2_____

Witness my hand and seal hereunto attached.

Notary Signature:_____

SEAL

My Commission expires: _____

***APPLICATIONS THAT ARE NOT SIGNED, NOT NOTARIZED, INCOMPLETE OR NOT ACCOMPANIED BY THE REQUIRED PROCESSING FEE WILL BE REJECTED.***

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## DISTRIBUTOR (PHARMACY-WHOLESALE) PERMIT–INFORMATION ABOUT OWNERSHIP

**Complete and submit one of these forms for each of the following persons listed on the *Application for Distributor (Pharmacy-Wholesale) Permit*:**

- **Designated Representative (DR) or most senior person responsible for facility operations, purchasing, and inventory control**
- **Supervisor of the DR or most senior person responsible for facility operations, purchasing and inventory control**
- **If not a publicly held company, *all* principals and owners who directly or indirectly own more than 10% interest in the company**

1. Name of Distributor:_____

2. Name: _____ _____ _____
   Last Name First Name Middle

3. Type of Interest in Distributor (check one):
   - ☐ Partner
   - ☐ Sole Proprietor
   - ☐ Individual with federal employee identification number
   - ☐ Corporate Officer – Position _____

4. Social Security Number: _____ 5. Date of Birth: _____

6. Mailing Address: _____

   _____ _____ _____
   City State Zip

7. Phone: _____ Email: _____

8. Has any state or federal agency taken any type of disciplinary action against you or is any such action pending? Yes ☐ No ☐ If yes, enclose a list of all disciplinary actions by state and federal agencies against you.

9. Have you ever been arrested, interviewed, interrogated, convicted, received a criminal summons, received a civil citation by any police/law enforcement agency, college/university or campus police or security agency? Yes ☐ No ☐ If yes, go to Question 10. If no, **skip to** Question 11.

   Note: This includes DUI's and all juvenile arrests and cases even if dismissed for any reason whatsoever. The *only* exceptions are minor traffic citations.

10. List each charge separately below and give details on a separate page.

| ARREST DATE | ORIGINAL CHARGE | LOCATION OF ARREST (city and state) | ARRESTING POLICE DEPARTMENT | DISPOSITION (e.g., guilty, not guilty, dismissed, etc.) |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

11. Has a criminal indictment, information, or complaint ever been returned against you, but for which you were not arrested or which you were named as an un-indicted co-party? Yes ☐ No ☐ If yes, give details on a separate page.

12. Have you ever received a pardon or expungement for any criminal offense? Yes ☐ No ☐ If yes, give details on a separate page. Include the charge, date, city, county and state.

13. Have you ever been, or are you now, on parole/probation to any court? Yes ☐ No ☐ If yes, give details on a separate page. Include the charges, the name of your parole/probation officer, location including city, county and state where probation was/is served.

14. Have you ever been civilly or criminally subpoenaed to appear to testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☐ If yes, give details on a separate page. Include the location and reason for being subpoenaed.

15. Have you ever been civilly or criminally subpoenaed to appear to testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☐ If yes, give details on a separate page. Include location and reason for being subpoenaed.

**Arrange for the Board office to receive a federal and state criminal background check sent directly from the State Bureau of Identification to the Board office. Complete an *Authorization to Release Information* form and follow the instructions on the form to submit your fingerprints.**

## AFFIDAVIT

I solemnly swear and affirm that the answers to the questions set forth in this application are true and correct.

**Signature:** _____ Date: _____

State of _____ Country of _____

Subscribed and sworn to before me this_____day of_____.2_____

Witness my hand and seal hereunto attached.

Notary Signature:_____

SEAL

My Commission expires: _____

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# LICENSE VERIFICATION FOR DISTRIBUTORS (PHARMACY-WHOLESALE)

## INFORMATION ABOUT APPLICANT

Representative of Distributor applying for Delaware licensure completes this section and forwards to the licensing agency for the state where the Distributor is located. Before forwarding form, check whether agency charges a fee for license verification.

1. Name of Distributor Applicant: _____

2. Mailing Address: _____

   _____ _____ _____
   City State Zip

3. Phone: _____ Email: _____

4. Type of Operation (check one): ☐ Distributor ☐ Manufacturer ☐ Repackager ☐ Relabeler

5. Type of Distribution Activities (check all that apply):

   ☐ Prescription ☐ Controlled Substances ☐ Over-the-Counter ☐ Cosmetics ☐ Dentifrices

**I authorize release of the information requested below to the State of Delaware Board of Pharmacy.**

Printed Name: _____ Title: _____

**Signature:** _____ Date: _____

## LICENSE VERIFICATION

Official of home State licensing agency completes this section.

1. License Number: _____ Issue Date: _____ Expiration Date: _____

2. Has this license been encumbered in any way? Yes ☐ No ☐ If yes, what type of encumbrance (check one):

   ☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation ☐ Lapsed

**ATTACH CERTIFIED COPIES OF ALL PERTINENT LEGAL DOCUMENTS.**

3. Has the applicant been convicted under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? Yes ☐ No ☐ If yes, explain: _____

   _____

4. Has the applicant furnished any false or fraudulent material in any application made in connection with drug manufacturing or distribution? Yes ☐ No ☐ If yes, explain: _____

   _____

5. Does your licensing agency routinely inspect the facility? Yes ☐ No ☐ If yes, complete this information:

   Date of Last Inspection: _____

   Has any inspection of the applicant resulted in deficiency ratings? Yes ☐ No ☐ If yes, explain: _____
   _____

6. Has the applicant met all licensing requirements of your State? Yes ☐ No ☐ If no, explain:_____

   _____

Printed Name of Official: _____ Title: _____

**Signature:** _____ Date: _____

**AFFIX OFFICIAL SEAL OF STATE LICENSING AGENCY BELOW.**

# Instructions for Requesting a Criminal Background Check

***Both state and federal criminal background checks are required.***

## Locations

**Kent County – Primary Facility**
State Bureau of Identification
Blue Hen Mall & Corporate Center
655 Bay Rd. Suite 1B
Dover, DE 19901
***Walk-ins accepted:*** Mon 9 am – 7 pm, Tue - Fri 9 am – 3 pm
Customer Service: (302) 739-2134

**New Castle County - Satellite Facility**
State Police Troop Two
100 LaGrange Ave
Newark, DE 19702
(Between Rts. 72 and 896 on Rt. 40)
***By appointment only***
Scheduling: (302) 739-2528 (local)
(800) 464-4357 (toll free)

**Sussex County – Satellite Facility**
Delaware State Police Troop Four
South DuPont Hwy & Shortley Rd. Georgetown DE 19947
(Across from DelDOT & the State Service Ctr.)
***By appointment only***
Scheduling: (302) 739-2528 (local)
(800) 464-4357 (toll free)

## Applicants Residing in Delaware

1. If you are using the New Castle or Sussex Counties locations, call **(800) 464-HELP (4357)** to schedule an appointment. No appointments are needed at the Kent County location.
2. Take the completed *Authorization for Release of Information* form to one of the offices listed above with the fee of $69.00, to cover both the State and Federal criminal checks. Money orders and credit cards other than American Express are accepted at all locations. New Castle and Kent Counties accept cash; Sussex County does not accept cash. *Personal checks are not accepted in any county.* As fees are subject to change, contact the agency where you plan to submit your forms for current fees.

## Out-of-State Applicants

1. You can be fingerprinted by your local police agency. All types of fingerprint cards are accepted. If your local police agency cannot provide a fingerprint card, call **(302) 739-2134** to request a fingerprint card.
2. Your *Authorization for Release of Information* form and fingerprint card must be complete. If identifying information is missing (such as name, date of birth, race, sex, etc.), your form will be returned. Send the *Authorization* form, fingerprint card, and certified check or money order (*personal checks are not accepted*) for $69.00 made payable to "Delaware State Police" to:

**Delaware State Police**
**State Bureau of Identification (SBI)**
**PO Box 430**
**Dover, DE 19903-0430**

⇨***ALLOW FOUR WEEKS FOR RECEIPT OF RESULTS.***

***DO NOT SEND THE FORM OR FEE TO THE BOARD OFFICE***

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## AUTHORIZATION FOR RELEASE OF INFORMATION

## CRIMINAL HISTORY RECORD CHECK FOR PROFESSIONAL LICENSURE APPLICANTS

*PLEASE PRINT OR TYPE ALL INFORMATION IN BLACK INK.*

**CHECK TYPE OF LICENSURE FOR WHICH APPLYING:**

- ☐ Adult Entertainment
- ☐ Deadly Weapons Dealer
- ☐ Dental
- ☐ Medical
- ☐ Nursing
- ☐ Nursing Home Administrator
- ☐ Pharmacy
- ☐ Texas Hold'em Dealer
- ☐ Other _____

**ENTER FULL CURRENT NAME:**

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Last Name | First Name | Middle Initial | Suffix (e.g., Jr., Sr.) |

**ENTER ALL OTHER NAMES USED IN THE PAST (including, but not limited to, maiden name, former married names, alternative spellings):**

1. _____
2. _____
3. _____
4. _____

## AUTHORIZATION TO RELEASE INFORMATION

As an applicant, I authorize release of any and all information that you have concerning me, including **CRIMINAL HISTORY RECORD INFORMATION** and other information of a confidential or privileged nature. I hereby release you, your organization, the State of Delaware and others from any liability or damage which may result from furnishing this information:

**SIGNATURE OF PERSON PRINTED:** _____ **Date:** _____

Phone: Home _____ Work _____

**MAIL THE RESULTS OF MY CRIMINAL HISTORY REQUEST TO:**

**Division of Professional Regulations**
**861 Silver Lake Boulevard, Suite 203**
**Dover DE 19904**
**SLC D420A**

**USE OF CRIMINAL HISTORY RECORD INFORMATION IS RESTRICTED BY LAW AND SHALL BE LIMITED TO THE PURPOSE FOR WHICH IT WAS GIVEN. MISUSE CONSTITUTES A CRIMINAL VIOLATION.**

Revised 12/2009